IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

HEART IMAGING TECHNOLOGIES, LLC,)
Plaintiff,)
v.) C.A. No
ARTERYS INC.,) JURY TRIAL DEMANDED
Defendant.)

COMPLAINT

Heart Imaging Technologies, LLC, ("Plaintiff" or "Heart IT"), for its Complaint against Defendant Arterys Inc. ("Defendant" or "Arterys"), alleges as follows:

THE PARTIES

- 1. Heart IT is a limited liability company organized under the laws of Delaware that maintains its principal place of business at 5003 Southpark Drive, Suites 130-140, Durham, North Carolina 27713.
- 2. Upon information and belief, Arterys Inc. is a corporation organized under the laws of the State of Delaware that maintains its principal place of business at 51 Federal Street, Suite 305, San Francisco, CA 94107.

JURISDICTION AND VENUE

- 3. This is an action for patent infringement arising under 35 U.S.C. § 271, et seq. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§1331 and 1338(a).
- 4. This Court has personal jurisdiction over the Defendant. Arterys is a Delaware corporation.
- 5. Venue in this District is proper pursuant to 28 U.S.C. §§1391(b) and (c) and 1400(b).

PLAINTIFF'S INTELLECTUAL PROPERTY

- 6. Heart IT has developed a unique and proprietary medical image conversion and management technology that enables medical images to be displayed and manipulated by an Internet browser.
- 7. On May 19, 2000, two university professors specializing in the field of medical imaging, Robert M. Judd, Ph.D. and Raymond J. Kim, MD, formed Heart IT. The company's mission is to develop innovative medical imaging tools for practicing physicians. Before Heart IT was formed, doctors were forced to study medical images, such as x-rays, on expensive workstations located at the hospital or medical office. Drs. Judd and Kim believed that these workstations could be replaced by standard Internet web browsers on any computer or handheld device, if some creative techniques were used to convert the image data to a browser compatible format without loss of diagnostic information.
- 8. On December 20, 2000, Heart IT filed U.S. patent application number 09/742,575 describing a medical image management system that allows any conventional Internet web browser to function as a medical imaging workstation.
- 9. Since 2001, Heart IT has sold picture archiving and communication systems ("PACS") to hospitals and research laboratories based on its unique and proprietary medical image conversion and management technology that enables medical images to be displayed and manipulated by an Internet browser without loss of diagnostic information.
- 10. On June 15, 2005, the U.S. Food and Drug Administration (FDA) granted Heart IT 510(k) approval to market its image management system as a medical device. Heart IT's FDA-approved medical image management system, WebPAX®, makes medical images available for display on Internet browsers (Exhibit A). On August 17, 2016, the FDA granted Heart IT a second 510(k) approval to market its medical image management system with expanded clinical

indications and medical image workstation functionality (Exhibit B). Currently, Heart IT also has approval to sell this product as a medical device across the European Union as well as in Canada, Brazil, and Australia. Since 2005, Heart IT has sold WebPAX® systems across the United States and around the world.

- 11. Heart IT has several patents covering its proprietary medical image conversion and management technology. These patents include U.S. Patent No. 6,934,698 ("the '698 Patent," or the "Diagnostic Quality Image" patent, attached as Exhibit C), U.S. Patent No. 7,457,656 ("the '656 Patent," or the "Server Side Rendering" patent, attached as Exhibit D), and U.S. Patent No. 8,166,381 ("the '381 Patent," or the "Workstation on a Browser" patent, attached as Exhibit E). These patents are collectively referred to herein as "the Asserted Patents." Heart IT is the sole owner of the Asserted Patents.
- 12. The '698 Patent contains four claims covering systems for producing diagnostic quality medical images that are compatible with Internet browsers. The '656 Patent contains 23 claims covering methods for performing server side rendering of medical images so that they are viewable in a browser. The '381 Patent contains 19 claims covering methods for simulating a medical image workstation in a webpage that is viewable on a browser.
- 13. On January 14, 2014, Merge Healthcare Incorporated (NASDAQ: MRGE) licensed Heart IT's '698, '656, and '381 patents. Merge Healthcare is a leading provider of clinical systems and innovations that seek to transform healthcare whose parent organization is International Business Machines (IBM).
- 14. On September 30, 2014, Viztek LLC (Viztek) licensed Heart IT's '698, '656, and '381 patents. Viztek is a leading provider of complete digital software and hardware imaging solutions whose parent organization is Konica Minolta Medical Imaging U.S.A, Inc.

15. On September 8, 2015, Vital Images, Inc. (Vital Images) licensed Heart IT's '698, '656, and '381 patents. Vital Images is a recognized leader in advanced medical image visualization software whose parent organization is Canon Medical Systems Corporation.

DEFENDANT'S INFRINGING CONDUCT

- 16. On September 8, 2016, Arterys submitted a 510(k) premarket notification for its Arterys 2.0 Software to the FDA (Exhibit F). Arterys's 510(k) application described Arterys 2.0 as offering "clinically-relevant and reproducible, quantitative data" for "clinical decision-making" using a standard Chrome browser.
- 17. On November 18, 2016, Arterys submitted a 510(k) premarket notification for its Arterys Cardio DL product (Exhibit G). The premarket notification stated that Arterys Cardio DL analyzes DICOM images from magnetic resonance (MR) scanners to provide diagnostic images for clinical decision-making using a standard Chrome browser.
- 18. On May 26, 2017, Arterys submitted a 510(k) premarket notification for its Arterys Viewer product (Exhibit H). The premarket notification stated that the Arterys Viewer stores, manipulates, and measures DICOM images and presents them to users in a web browser.
- 19. On July 26, 2018, Arterys submitted a 510(k) premarket notification for its Arterys MICA product (Exhibit I). The premarket notification stated that the Arterys MICA product is a medical diagnostic application that displays, processes, stores and transfers DICOM and non-DICOM medical data to a web browser client.
- 20. On August 8, 2018, Heart IT sent a letter to Arterys notifying it of the Asserted Patents and explaining that, based on publicly available information, several of Arterys's products appeared to be covered by certain claims of the Asserted Patents.

- 21. Thereafter, Heart IT and Arterys exchanged emails and phone calls in an attempt to conclude a licensing agreement. The negotiations were unsuccessful.
- 22. On February 7-9, 2019, Arterys attended the annual meeting of the Society for Cardiovascular Magnetic Resonance (SCMR) in Seattle, WA. During the SCMR meeting, Arterys sponsored a trade show booth immediately adjacent to Heart IT's trade show booth. The Arterys trade show booth publicly advertised that their products include the unique features covered by Heart IT's '698, '656, and '381 patents.
- 23. On February 7, 2019, the first day of the SCMR trade show meeting, Arterys conducted two "hands-on" workshops for SCMR attendees. According to Arterys's advertising materials, these workshops "allow attendees to analyze studies using the cloud-based Arterys Medical Imaging Cloud AI (MICA) Platform." During these workshops, Arterys publicly demonstrated that their products include the unique features covered by Heart IT's '698, '656, and '381 patents.
- 24. On February 8, 2019, the second day of the SCMR trade show meeting, Arterys participated in a competitive "face-off" designed to allow different companies to demonstrate the capabilities of their products to all SCMR 2019 attendees. During its presentation, Arterys publicly demonstrated that their products include the unique features covered by Heart IT's '698, '656, and '381 patents.
- 25. On information and belief, Arterys 2.0 Software, Arterys Cardio DL, Arterys Viewer, and Arterys MICA (the "Accused Products") each infringe one or more claims of the Asserted Patents.

COUNT I

INFRINGEMENT OF THE '698 PATENT

- 26. Heart IT realleges and incorporates herein the foregoing paragraphs of this Complaint.
- 27. Heart IT owns all right, title and interest in the '698 Patent and has not licensed or otherwise granted any right under the '698 Patent to Defendant.
- 28. The Accused Products receive medical image data from various image data sources, such as MRI or CT scan machines, and convert the data to a browser compatible format so that they can be viewed on a user's computer without installing any software. This "zero download" or "zero client" capability is an important selling feature of the Accused Products.
- 29. Arterys has directly infringed and continues to directly infringe the '698 Patent by making, using, selling, licensing, offering for sale or license, and/or importing into the United States medical image conversion and management systems, including the Accused Products, that infringe at least claim 1 of the '698 Patent in violation of 35 U.S.C. §271(a).
 - 30. Claim 1 of the '698 Patent states:
 - 1. A medical Image management system comprising:
 - a transfer engine for receiving medical image data from an image data source:
 - a converter engine for converting medical image data to a browser compatible image format connected to receive medical image data from the transfer engine, wherein the converter engine comprises:
 - a decoder engine for extracting image pixel data from image data;
 - a physiologic knowledge engine for reducing the image pixel data without loss of diagnostic data connected to receive the extracted pixel data; and
 - an encoder engine for converting image pixel data to a browser compatible format connected to receive image pixel data, whereby

image data is converted to the browser compatible format without loss of diagnostic data; and

- a post engine for posting the browser compatible image to a database connected to receive converted image data.
- 31. By way of example, and not limitation, Defendant's direct infringement of Claim 1 of the '698 Patent is described below.
- 32. On information and belief, each of the Accused Products sold by Defendant is a medical image management system that receives medical image data from an image data source, such as an MRI machine, and converts the medical image data from DICOM format to a browser compatible format. For example, the Arterys Software v2.0 supports DICOM 3.0 image input to obtain cardiovascular images acquired from MRI scanners, and converts the images so that they can be viewed using a browser without loss of diagnostic data.
- 33. On information and belief, each of the Accused Products performs the conversion of medical images by extracting image pixel data from the image data, reducing the image pixel data without loss of diagnostic data, and converting the image pixel data to a browser compatible format without loss of diagnostic data. For example, the Arterys Software v2.0 extracts pixel data from the DICOM image input, automatically reduces image pixel data and adjusts Window/Level, frame rate, and other variables in accordance with physiologic principles, and converts the image to a browser compatible format.
- 34. On information and belief, each of the Accused Products posts the browser compatible image to a database. For example, Arterys Software v2.0 provides a longitudinal view of patient records that is stored on a database of converted images.
- 35. In addition, Arterys has indirectly infringed and continues to indirectly infringe the '698 Patent, after receiving notice of its infringement, by knowingly and intentionally inducing its customers to use these systems in violation of 35 U.S.C. §271(b). For example,

Arterys conducted "hands-on" workshops at the SCMR trade show in February 2019 that publicly demonstrated the features of the Accused Products that infringe the '698 Patent and encouraged attendees to purchase and use them in a manner that infringes the '698 Patent.

- 36. Arterys has also indirectly infringed and continues to indirectly infringe the '698 Patent by knowingly and intentionally contributing to infringement of the patent under 35 U.S.C. §271(c) with knowledge of the '698 Patent. Arterys Software v2.0 is a medical image management system with no substantial noninfringing use, and use of the system by Arterys's customers has no other purpose than to operate in a manner that is a direct infringement of the '698 Patent.
- 37. On information and belief, Arterys has been aware of the '698 Patent since before it began its infringement, and has been on actual notice that these systems infringe the '698 Patent since at least August 10, 2018, when it received a letter from Heart IT notifying it of the Asserted Patents. Accordingly, Arterys's infringement of the '698 Patent is willful, and its conduct makes this an exceptional case pursuant to 35 U.S.C. §285.
- 38. As a result of Defendant's aforementioned conduct, Heart IT has suffered and continues to suffer substantial damage and irreparable harm constituting an injury for which Heart IT has no adequate remedy at law. Accordingly, only a permanent injunction from this Court can prevent Heart IT's further irreparable harm at the hands of Defendant.

COUNT II

INFRINGEMENT OF THE '656 PATENT

- 39. Heart IT realleges and incorporates herein the foregoing paragraphs of this Complaint.
- 40. Heart IT owns all right, title and interest in the '656 Patent and has not licensed or otherwise granted any right under the '656 Patent to Defendant.

41. Arterys has directly infringed and continues to directly infringe the '656 Patent by making, using, selling, licensing, offering for sale or license, and/or importing into the United States medical image conversion and management systems, including the Accused Products, that infringe at least claim 1 of the '656 Patent in violation of 35 U.S.C. §271(a).

42. Claim 1 of the '656 Patent states:

1. A method of managing medical information comprising:

receiving at least one digital medical image in a format that is incompatible with viewing in an Internet web browser;

predetermining without user input at least one image display setting of the at least one digital medical image to permit medical diagnosis by the user of the at least one digital medical image having the at least one image display setting applied thereto;

converting the at least one digital medical image using the predetermined at least one image display setting,

wherein the converted at least one digital medical image is compatible with viewing in an Internet web browser and retains its original resolution.

- 43. By way of example, and not limitation, Defendant's direct infringement of Claim 1 of the '656 Patent is described below.
- 44. On information and belief, each of the Accused Products is a medical image management system that receives medical image data from an image data source, such as an MRI machine, and converts the medical image data from DICOM format to a browser compatible format. For example, Arterys Software v2.0 supports DICOM 3.0 image input to obtain cardiovascular images acquired from MRI scanners, and converts the images so that they can be viewed using a web browser.
- 45. On information and belief, each of the Accused Products predetermines without user input at least one image display setting of the digital medical image to permit medical

diagnosis by the user. For example, Arterys Software v2.0 predetermines the Window/Level of digital medical images to permit medical diagnosis by the user.

- 46. On information and belief, each of the Accused Products converts the at least one digital medical image using the predetermined at least one image display setting to a browser compatible format, wherein the converted at least one digital medical image is compatible with viewing in an Internet web browser and retains its original resolution. For example, Arterys Software v2.0 converts DICOM images to a browser compatible format using the predetermined image settings and the images retain their original resolution.
- 47. In addition, Arterys has indirectly infringed and continues to indirectly infringe the '656 Patent, after receiving notice of its infringement, by knowingly and intentionally inducing its customers to use these systems in violation of 35 U.S.C. §271(b). For example, Arterys conducted "hands-on" workshops at the SCMR trade show in February 2019 that publicly demonstrated the features of the Accused Products that infringe the '656 Patent and encouraged attendees to purchase and use them in a manner that infringes the '656 Patent...
- 48. Arterys has also indirectly infringed and continues to indirectly infringe the '656 Patent by knowingly and intentionally contributing to infringement of the patent under 35 U.S.C. §271(c) with knowledge of the '656 Patent. Arterys Software v2.0 is a medical image management system with no substantial noninfringing use, and use of the system by Arterys's customers has no other purpose than to operate in a manner that is a direct infringement of the '656 Patent.
- 49. Arterys has been on actual notice that its Accused Products infringe the '656 Patent since at least August 10, 2018. Accordingly, Arterys's infringement of the '656 Patent is willful, and its conduct makes this an exceptional case pursuant to 35 U.S.C. §285.

50. As a result of Defendant's aforementioned conduct, Heart IT has suffered and continues to suffer substantial damage and irreparable harm constituting an injury for which Heart IT has no adequate remedy at law. Accordingly, only a permanent injunction from this Court can prevent Heart IT's further irreparable harm at the hands of Defendant.

COUNT III

INFRINGEMENT OF THE '381 PATENT

- 51. Heart IT realleges and incorporates herein the foregoing paragraphs of this Complaint.
- 52. Heart IT owns all right, title and interest in the '381 Patent and has not licensed or otherwise granted any right under the '381 Patent to Defendant.
- 53. Arterys has directly infringed and continues to directly infringe the '381 Patent by making, using, selling, licensing, offering for sale or license, and/or importing into the United States medical image conversion and management systems, including the Accused Products, that infringe at least claim 1 of the '381 Patent in violation of 35 U.S.C. §271(a).
 - 54. Claim 1 of the '381 Patent states:
 - 1. A method of managing medical information, comprising:

receiving at a first computer a plurality of image series resulting from a patient medical imaging procedure, each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser;

providing a pointer associated with the patient medical imaging procedure;

in response to user selection of the pointer at a second computer,

providing an Internet web page for display in an Internet web browser on the second computer, the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the user interface comprising a rectangular grid of one or more rows and one or more columns for simultaneously displaying a plurality of navigational images in the user interface of the Internet web page, and

providing to the user the plurality of navigational images for display in the user interface of the Internet web page, the plurality of navigational images corresponding to different ones of the image series from the patient medical imaging procedure, the plurality of navigational images comprising a format that is compatible for displaying in an Internet web browser without requiring software executing outside the Internet web browser on the second computer, the plurality of navigational images being converted to a browser compatible format before being transmitted over the Internet; and

in response to user selection of one of the plurality of navigational images, providing to the user the one or more digital medical images of the image series associated with the selected one of the navigational images for display in the user interface of the Internet web page, the one or more digital medical images comprising a format that is compatible for displaying in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the one or more digital medical images providing medical information to the user, the one or more digital medical images being converted to a browser compatible format before being transmitted to the second computer,

wherein the medical image workstation enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser.

- 55. By way of example, and not limitation, Defendant's direct infringement of Claim 1 of the '381 Patent is described below.
- 56. On information and belief, each of the Accused Products is a medical image management system that receives a plurality of image series resulting from a patient medical imaging procedure, each image series comprising one or more digital medical images in a format that is incompatible with displaying in an Internet web browser. For example, Arterys Software

v2.0 receives images series generated by MRI scanners in DICOM format that cannot be viewed using a web browser.

- 57. On information and belief, each of the Accused Products provides a pointer for use in selecting medical imaging procedures. For example, Arterys Software v2.0 provides a Worklist of studies that may be selected using the cursor of the user's browser.
- 58. On information and belief, each of the Accused Products, in response to selection of a medical imaging study, provides an Internet web page for display in an Internet web browser on the user's computer, the Internet web page forming a user interface for a medical image workstation when displayed in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the user interface comprising a rectangular grid of one or more rows and one or more columns for simultaneously displaying a plurality of navigational images in the user interface of the Internet web page. For example, the user interface of Arterys Software v2.0 is a web page that includes a rectangular grid of navigational images representing the available series or workflows.
- 59. On information and belief, each of the Accused Products, in response to selection of a medical imaging study, also provides to the user the plurality of navigational images for display in the user interface of the Internet web page, the plurality of navigational images corresponding to different ones of the image series from the patient medical imaging procedure, the plurality of navigational images comprising a format that is compatible for displaying in an Internet web browser without requiring software executing outside the Internet web browser on the second computer, the plurality of navigational images being converted to a browser compatible format before being transmitted over the Internet. For example, the user interface of Arterys Software v2.0 provides thumbnail navigational images corresponding to different image

series from a study, and the thumbnails are compatible for displaying in the user's Chrome web browser without requiring additional software executing outside the Chrome browser.

- 60. On information and belief, each of the Accused Products provides the user the one or more digital medical images of the image series associated with the selected one of the navigational images for display in the user interface of the Internet web page, the one or more digital medical images comprising a format that is compatible for displaying in the Internet web browser without requiring software executing outside the Internet web browser on the second computer, the one or more digital medical images providing medical information to the user, the one or more digital medical images being converted to a browser compatible format before being transmitted to the second computer. For example, Arterys Software v2.0 provides users with the images associated with each image series in a format that is compatible for displaying in the user's Chrome web browser without requiring additional software executing outside the Chrome browser.
- 61. On information and belief, the medical image workstation generated by each of the Accused Products enables user navigation among the plurality of navigational images and the one or more digital medical images of the image series to permit medical diagnosis from the one or more digital medical images without requiring software executing outside the Internet web browser. For example, Arterys Software v2.0 allows users to navigate among the navigational images and the images of the series to permit medical diagnosis, without requiring additional software executing outside the Chrome browser.
- 62. In addition, Arterys has indirectly infringed and continues to indirectly infringe the '381 Patent, after receiving notice of its infringement, by knowingly and intentionally inducing its customers to use these systems in violation of 35 U.S.C. §271(b). For example,

Arterys conducted "hands-on" workshops at the SCMR trade show in February 2019 that publicly demonstrated the features of the Accused Products that infringe the '381 Patent and encouraged attendees to purchase and use them in a manner that infringes the '381 Patent.

- 63. Arterys has also indirectly infringed and continues to indirectly infringe the '381 Patent by knowingly and intentionally contributing to infringement of the patent under 35 U.S.C. §271(c) with knowledge of the '381 Patent. Arterys Software v2.0 is a medical image management system with no substantial noninfringing use, and use of the system by Arterys's customers has no other purpose than to operate in a manner that is a direct infringement of the '381 Patent.
- 64. As a result of Defendant's aforementioned conduct, Heart IT has suffered and continues to suffer substantial damage and irreparable harm constituting an injury for which Heart IT has no adequate remedy at law. Accordingly, only a permanent injunction from this Court can prevent Heart IT's further irreparable harm at the hands of Defendant.

JURY DEMAND

Heart IT hereby demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, as to the Counts set forth above, Heart IT requests that this Court enter a judgment in favor of Heart IT as follows:

- A. Finding that Defendant has directly and indirectly infringed each of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), and (c);
- B. Preliminarily and permanently enjoining and restraining Defendant, and its parents, subsidiaries, holding companies, licensees, owners, directors, officers, partners, assigns, related entities, affiliates, predecessors, successors, employees,

representatives, trustees, receivers, agents and any other persons or entities acting on its behalf or with its authority, from making, using, selling, licensing, offering for sale or license, and/or importing into the United States medical image conversion and management systems, including Arterys Viewer, Arterys Cardio DL, Arterys MICA, and Arterys Software 2.0, that infringe one or more of the Asserted Patents;

C. Awarding Heart IT damages adequate to compensate it for Defendant's infringement, but in no event less than a reasonable royalty for Defendant's use of the inventions claimed in the Asserted Patents, together with interest and costs;

D. Finding that Defendant has willfully infringed the Asserted Patents and awarding treble damages to Heart IT with interest;

E. Finding that this is an exceptional case under 35 U.S.C. §285 and awarding Heart IT its reasonable attorney's fees and costs; and

F. Awarding such other and further relief as this Court may deem equitable under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/Karen Jacobs

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